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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/169,776	10/08/98	KARAKASOGLU A	A-65600/HCH

QM12/0813

FLEHR HOHBACH TEST ALBRITTON & HERBERT
SUITE 3400
FOUR EMBARCADERO CENTER
SAN FRANCISCO CA 94111-4187

EXAMINER	
ASTORINO, M	
ART UNIT	**PAPER NUMBER**
3736	3

DATE MAILED: 08/13/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/169,776	Karakasoglu et al.
Examiner	**Group Art Unit**
Michael Astorino	3736

☒ Responsive to communication(s) filed on *Oct 8, 1998*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-21* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-21* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on *Oct 8, 1998* is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *2*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Double Patenting

The following non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. In re Sarett, 327 F.2d. 1005, 140 USPQ 474 (CCPA 1964); In re Schneller, 397 F.2d. 350, 158 USPQ 210 (CCPA 1968); In re White, 405 F.2d. 904, 160 USPQ 644 (CCPA 1969); In re Thorington, 418 F.@d. 528, 163 USPQ 644 (CCPA 1969),; In re Vogel, 422 F.2d. 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d. 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.@d. 887, 225 USPQ 645 (Fed Cir. 1985); and In re Goodman, 29 USPQ 2d 2010 (Fed Cir 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(b) would overcome an actual or provisional rejection on non-statutory double patenting grounds, provided that the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.78(d).

Claims 1-21 are provisionally rejected under the judicially created doctrine of double patenting.

The subject matter recited in claims 1-21 of the present application was fully disclosed in US Patent 5,797,852. The allowance of the above listed claims would extend the rights to exclude already granted in the patent - that right to exclude covering the invention "comprising ABCX". The transitional phrase comprising does not exclude the presence of elements other than

A, B, C, X in the claim. Because of the phrase "comprising" the patent not only provides protection ABCX, but also extends patent coverage to the disclosed combination - ABCXY. Likewise, if allowed, the claim(s) of the present application, because of the phrase "comprising" not only would provide patent protection to the claimed combination ABCY, but also would extend patent coverage to the combination ABCXY, already disclosed and covered by the patent. Thus, the controlling fact is that patent protection for the invention, fully disclosed in and covered by US Patent 5,797,852 would be extended by allowance of these claims in the present application.

Furthermore, there is no reason why applicant could not have prosecuted the present claims during prosecution of the US Patent 5,797,852.

This is a provisional rejection in that the claims have not in fact been patented.

For a more detailed discussion of this double patenting rejection, see MPEP 804(2), under the heading "Non-obvious type."

Specification

1. The disclosure is objected to because of the following informalities: The specification is missing titles between sections. The section headings are listed below for convenience. Appropriate correction is required.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.

(b) Cross-References to Related Applications.

(c) Statement Regarding Federally Sponsored Research or Development.

(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).

(e) Background of the Invention.

1. Field of the Invention.

2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.

(g) Brief Description of the Several Views of the Drawing(s).

(h) Detailed Description of the Invention.

(I) Claim or Claims (commencing on a separate sheet).

(j) Abstract of the Disclosure (commencing on a separate sheet).

(k) Drawings.

(l) Sequence Listing (see 37 CFR 1.821-1.825).

Drawings

2. The drawings are objected to because on page 4, line 27, the specification recites a reference number (11) not displayed in drawings. Correction is required.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In regards to claims 1 and 15, the claims are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite an acoustical device positioned on the face in the vicinity of the nose and/or mouth. This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite that an acoustical device is adapted to be positioned on the face in the vicinity of the nose and/or mouth.

In regards to claim 10, the claims are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 10 recites at least certain of said ports underlie the nostrils of the nose. This recites a positive relationship to the human body.

However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite that at least certain of said ports are adapted to underlie the nostrils of the nose.

In regards to claim 11, the claims are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 11 recites said body of the device includes a portion extending over the mouth of the patient. This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite that said body of the device includes a portion is adapted to extend over the mouth of the patient.

In regards to claim 12, the claims are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 12 recites said portion of the body overlying the mouth of the patient. This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite that said portion of the body adapted to overly the mouth of the patient.

In regards to claim 13, the claims are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 13 recites said means for securing the device to the patient includes loops extending around the ears of the patient and secured to the body. This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the

claim to recite that said means for being adapted to secure the device to the patient includes loops adapted to extended around the ears of the patient and secured to the body.

In regards to claim 14, the claims are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 14 recites wherein said body includes at least one port underlying each of the nostrils of the nose and at least one port opening in the vicinity of the mouth of the patient. This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, applicant should amend the claim to recite that wherein said body includes at least one port adapted to underlie each of the nostrils of the nose and at least one port adapted to open in the vicinity of the mouth of the patient.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In independent claims 1 and 15 the phrase, in the vicinity of the nose and/or mouth, is vague and indefinite.

8. In dependent claims 5, 14, and 16 the phrase, in the vicinity..., is vague and indefinite.

9. Claim 16 recites the limitation "the first named and additional output signals" in line 4. There is insufficient antecedent basis for this limitation in the claim.

10. In dependent claim 16 the term, substantially free, in line 6 is indefinite.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 1-5, 9-10 and 15-16, are rejected under 35 U.S.C. 102(a) as being anticipated by Sullivan et al.

In regards to claims 1-5, 9-10, and 15-16, Sullivan et al. discloses monitoring breath by sensing air from a nose mask (12) comprising a microphone (11) to sense air flow, and a sensor

exposed to the acoustical duct for sensing turbulence (column 8, lines 55-64) and (10 and column 12, lines 36-46) providing a digital combined real time signal indicative of the patient breathing.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 6-8 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan et al.

Sullivan does not disclose providing a measure for respiratory sound intensity. However it is obvious to one in the art that once a air flow signal is received the signal can be manipulated in various ways to display various results. Hence it is the examiner's position that changes units of measure is not considered an patentable material. Further Sullivan et al. discloses generating a signal after a sequence of snores. Hence each sequence is considered a predetermined time interval (column 9, lines 58-67).

15. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan et al. as applied to claim 1 above, and further in view of Derrick.

Sullivan et al. does not particularly disclose that the nose mask extends over the mouth. However it is well documented in the art that respiratory rates and tests can be taken from the nose, mouth or both. This can be seen in Derrick wherein the patients nasal passage and mouth is covered with a sensing apparatus (figures 1-2) that is which secured around the ears. It would have been obvious to one in the art at the time of the invention to combine Sullivan et al. and Derrick to maintain a more efficient diagnosing apparatus.

16. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sullivan et al. as applied to claim 15 above, and further in view of Raviv et al.

Sullivan et al. does not particularly disclose a display is used in the invention, however it is obvious to one in the art that monitors are well known in the art when analyzing data. As an example of analyzing and displaying sleep data taken from patient Raviv et al. discloses a display to enhance data analysis (column 4, lines 7-10). It would have been obvious to one in the art at the time of the invention to combine Sullivan et al. and Raviv et al. to maintain a more efficient diagnosing apparatus.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Berthon-Jones ('345), Sheehan et al. ('885) and Rapoport et al. ('066).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Astorino whose telephone number is (703) 306-9067.

M. Astorino

August 3, 1999

CARY O'CONNOR
SUPERVISORY PATENT EXAMINER
GROUP 3700